

## **R E M A R K S**

In the present communication, Claim 28 was amended and Claims 30-32 were cancelled. As such, Claims 28-29 are currently pending. The Examiner's rejections are as follows:

I. Claims 28-32 were rejected under 35 U.S.C. 112, first paragraph, as allegedly non-enabled; and

II. Claims 28-32 were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Dombrowaki et al. (U.S. Pat. 5,759,842) in view of Bell (U.S. Pat. 5,663,161).

### **I. Enablement Rejection**

The Examiner rejected Claims 28-32 under 35 U.S.C. 112, first paragraph, as allegedly non-enabled (Office Action, page 2). Applicants respectfully disagree with this rejection. Nonetheless, in order to expedite the prosecution of the present application, without acquiescing to the Examiner's rejection, while reserving the right to prosecute the original or similar claims in the future, Applicants have amended the claims. In particular, Claim 28 has been amended to recite that the reverse transcriptase inhibitor is selected from the group consisting of: zidovudine (AZT), dideoxycytidine, and 2',3'-dideoxyinosine. Applicants respectfully submit that the claims are fully enabled for employing an integrase inhibitor and one of these specific reverse transcriptase inhibitors. As such, Applicants request that this rejection be withdrawn.

### **II. Obviousness Rejection over Dombrowaki et al. in view of Bell**

The Examiner rejected Claims 28-32 under 35 U.S.C. 103(a) as allegedly obvious over Dombrowaki et al. in view of Bell. (Office Action, page 6). In particular, the Examiner cites Dombrowaki et al. as teaching the combined use of HIV integrase inhibitors and reverse transcriptase inhibitors, such as AZT (zidovudine). The Examiner admits that Dombrowaki et al. does not teach administration of the combination of AZT and an integrase inhibitor to HIV strains resistant to AZT (Office Action, page 7). In an attempt to make up for this deficiency, the Examiner cites Bell et al. as teaching:

"[T]reating HIV strains resistant to AZT at different stages in the HIV life cycle (column 1 line 19-34). Specifically, an integrase inhibitor can be used in combination with reverse transcriptase inhibitors (column 23 lines 42-64), where AZT, ddI and ddC are previously known reverse transcriptase inhibitors (column 1 lines 24-26).

Applicants respectfully submit that the Bell reference, as explained below, does not teach administering AZT and an integrase inhibitor to an AZT resistant patient.

The Background section of Bell et al. cited by the Examiner indicates that many patients develop HIV resistant to AZT and then suggests that there is a need to develop drugs (other than those similar to AZT) that act at different stages of the virus life-cycle (Bell et al., column 1, lines 28-34). This teaching, however, does not teach that once a patient has developed AZT resistant HIV, that one should still administer AZT in combination with an integrase inhibitor. Instead, this passage merely indicates that combinations of drugs should be employed *that work* at different stages of the virus life cycle (i.e., the combination of drugs should both individually be expected to *work* to destroy or dis-able the virus - there is no suggestion to use a drug the virus is known to be resistant to).

The second portion of Bell et al. cited by the Examiner also does not teach administering a reverse transcriptase inhibitor that the patient is known to be resistant to. Instead, this section simply re-states the teaching of the background that combinations of anti-HIV compounds should be used together:

Whether CADA is an uncoating inhibitor, an integrase inhibitor or operates by another mechanism, its discovery leads to a new class of drugs complementing inhibitors of reverse transcriptase and protease, used individually or in combination therapy. (column 23, lines 53-57).

Again, this passage merely recites the combination of various drug classes and does not teach or suggest that if a patient has become resistant to a particular compound that such a compound should (and could) nonetheless be used in combination with an integrase inhibitor.<sup>1</sup> As such, Applicants submit that the combination of Dombrowaki et al. and Bell does not teach or suggest all the elements of the amended claims. Therefore, this rejection should be withdrawn.

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<sup>1</sup> Applicants further note that the compounds in Bell (e.g., CADA) are NOT integrase inhibitors, as it was later determined by Vermieire (and Bell) et al. that CADA is a CD4 receptor inhibitor (see, Mol. Pharm., 63:203-210, 2003).

**CONCLUSION**

Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned at 608-218-6900.

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